PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Inventors: Wolfgang Guba, et. al.

Application No.: 10/634,431

Filed: August 5, 2003

Technology Center: 1600

Attorney Docket No. 21152

Art Unit: 1626

Examiner: Laura Stockton

FOR: **AMINOTHIAZOLE DERIVATIVES**

APPEAL BRIEF OF APPELLANT

Nutley, New Jersey 07110
June 20, 2006

Mail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This is an appeal under 35 USC §134 pursuant to 37 CFR §41.37 from the final rejection of claims 1-16. This Brief is submitted in triplicate, along with a Petition for a two-month extension of time and a Request to Charge Deposit Account for any fees in connection with this appeal to Deposit Account No. 08-2525.

I. REAL PARTY IN INTEREST

The rights to this application have been assigned to Hoffmann-La Roche Inc.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF THE CLAIMS

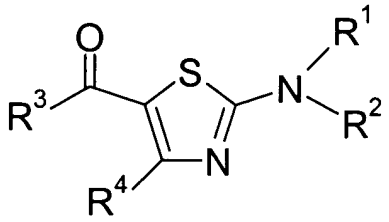
Claims 1-16 are pending. Claims 1-16 are finally rejected and are presented here on appeal. A copy of appealed claims 1-16 is attached hereto as Appendix A.

IV. STATUS OF AMENDMENTS

The rejection of claims 1-16 under 35 USC §§ 103 and 112 were made final in the Office Action of August 17, 2005. An Amendment was filed under 37 CFR §1.116 on January 12, 2006, amending claims 1, 4, 5 and 12, thereby rendering the Section 103 rejection moot. The Advisory Action of February 16, 2006 removed the Section 103 rejection but maintained the Section 112 rejection of claims 1-16.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

This invention is directed to a compound of formula (I):



(I)

wherein:

R^1 is aryl or heteroaryl, wherein at least one of the two meta positions of each aryl and heteroaryl group is substituted with R^5;

R^2 is hydrogen, alkyl or cycloalkyl;

R^3 is cycloalkyl or aryl , wherein at least one of the two ortho positions of each cycloalkyl or aryl group is substituted with R^6;

R^4 is hydrogen, alkyl or cycloalkyl;

R^5 is hydrogen, cyano, trifluoromethyl, alkyl-SO_2-, amino-SO_2-, halogen, alkoxy, alkylcarbonyl or aminocarbonyl; and

R^6 is hydrogen, halogen, cyano, nitro, trifluoromethyl, alkyl, alkoxy, hydroxy or alkoxycarbonyl;

or a pharmaceutically acceptable salt or ester thereof;

with the proviso that one of R^5 and R^6 is not hydrogen and with the proviso that the following compounds are excluded:

(2,4-dichlorophenyl)-[2-[(3,4-dichlorophenyl)amino]-5-thiazolyl]-methanone,

(3,4-dichlorophenyl)-[2-[(3,4-dichlorophenyl)amino]-5-thiazolyl]-methanone,

[2-[(3,4-dichlorophenyl)amino]-5-thiazolyl]phenyl-methanone,

(4-bromophenyl)-[2-(3,4-dichlorophenyl)amino]-5-thiazolyl]-methanone,

(4-chlorophenyl)-[2-[3,4-dichlorophenyl)amino]-5-thiazolyl]-methanone,

[2-[(3,4-dichlorophenyl)amino]-5-thiazolyl](4-fluorophenyl)-methanone,

[2-[(2-chlorophenyl)amino]-5-thiazolyl](2,4-dichlorophenyl)-methanone and

(2,4-dichlorophenyl)-[2-(phenylamino)-5-thiazolyl-methanone.

The compounds of the invention are neuropeptide ligands preferably used for the treatment of eating disorders and obesity.

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-16 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description. The Examiner alleges that the proviso in claim 1 adds new matter.

The appealed grounds for rejection apply to all rejected claims, i.e., claims 1-16.

VII. ARGUMENT

This Appeal involves whether an amendment to remove certain species of compounds of formula (I) by a proviso, thereby claiming *less* than the full scope of the disclosure, violates the written description requirement by introducing new matter. Appellants believe that the proviso now recited in claim 1 is fully supported by the specification and does not introduce new matter. Appellants are simply claiming less than the full scope of their disclosure, a perfectly legitimate exercise since it is for the inventors to decide what bounds of protection they will seek. Moreover, Appellants respectfully submit that In re Johnson, 194 U.S.P.Q. 187 (C.C.P.A. 1977), provides legal precedent for the addition of this proviso.

According to the C.C.P.A. in Johnson, a limitation of the members of a genus originally described in the specification can be sufficiently supported by the original specification that taught the entire genus. As in the instant case, the proviso in Johnson limited rather than expanded the scope of the invention. Specifically, the applicants in Johnson narrowed their claims to avoid having them read on a lost interference count. The court held that the provisions of §112, first paragraph, were not violated, stating that there was sufficient written description supporting the claims in the absence of the limitation, and thus "the specification, having described the whole, necessarily described the part remaining." Id. at 196. According to the C.C.P.A., applicants were merely excising species, *not* creating new matter. Id.

The fact pattern in the present case is analogous to the fact pattern in Johnson. As in Johnson, Appellants are including provisos in the claims that exclude certain compounds, not introducing new matter. Additionally, in Johnson and in the present case, a broad and generic disclosure of the excluded components is set forth: in Johnson, a broad class of precursor compounds with specific examples was disclosed; in the present specification, a broad class of compounds of formula (I), including specific examples, were disclosed. Based on these common underlying factors, Appellants respectfully submit that Johnson is analogous to the present case.

The holding in Johnson is not limited to permitting only the exclusion of compositions which have been specifically recited in the specification. Rather, Johnson requires only that a "broad and complete generic disclosure, coupled with extensive examples fully supportive of the limited genus now claimed" be present in order to support the exclusion of specific compositions. In re Johnson, 194 U.S.P.Q. at 196.

Appellants respectfully submit that a broad and complete generic disclosure is set forth in the instant application. Each of the compounds of formula (I) were fully defined in the specification as originally filed. Thus, the specification and claims as originally filed set forth specific compounds and compositions that are not excluded by the new provisos recited in the claims. As in Johnson, this fact provides sufficient evidence that Appellants considered the subject matter of the presently claimed invention to be within the scope of their invention, and the new provisos are not new matter for this reason alone.

Moreover, adequate written description, particularly with respect to provisos, does not require literal support for the claimed invention. In re Wertheim, 191 U.S.P.Q. 90, 98 (C.C.P.A. 1976). The originally filed disclosure provides support as long as it would have reasonably conveyed to one having ordinary skill in the art that an Appellant had possession of the concept of what is now claimed. In re Anderson, 176 U.S.P.Q. 331, 336 (C.C.P.A. 1973).

The rationale of Wertheim approaches the present situation. In Wertheim, the C.C.P.A. cautioned against letting form triumph over substance by eliminating the right of an Appellant to rely on an otherwise patentable species. *See* In re Wertheim, 191 U.S.P.Q. at 97. The present situation, like that in Wertheim, does not involve the introduction of a new concept. Rather, the present situation involves a reliance on species within the originally claimed genus. Wertheim approved that approach, and the Examiner has no reason to treat Appellants under any other standard.

Indeed, Wertheim recites the proposition that an Appellant is allowed to change his view of the invention during the prosecution of his application:

> That what appellants claim as patentable to them is *less* than what they describe as their invention is not conclusive if their specification also reasonably describes that which they do claim. Inventions are constantly made which turn out not to be patentable, and Appellants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable.

Id. at 97 (emphasis in original). Similarly, "[i]t is not necessary that the application describe the claim limitations exactly, . . . but only so clearly that persons of ordinary skill in the art will recognize [it] from the disclosure[.]" Id. at 96.

That is, it is not necessary that the specification as originally filed support the claims as limited by the proviso word for word. In fact, it is well-settled in the case law that claimed subject matter need not be described in *ipsis verbis* in the original specification in order to satisfy the written description requirement. See, e.g., In re Edwards, 196 U.S.P.Q. 465, 467 (C.C.P.A. 1978). Instead, as long as the scope of the invention is recognizable to one skilled in the art, the limiting amendment is not a problem. See, e.g., Ex parte Parks, 30 U.S.P.Q.2d 1234 (B.P.A.I. 1994).

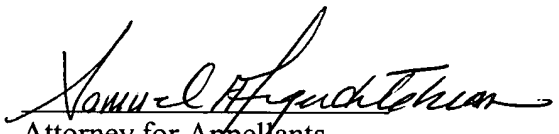
Thus, the instant narrowing proviso to claim 1 is not a new matter violation of Section 112, first paragraph. Consequently, the Examiner's rejection should be removed and the pending claims be allowed to progress to issuance.

CONCLUSION

In view of the forgoing arguments and the facts of record, Appellants submit that all pending claims are in condition for allowance and request that the Board direct the Examiner to allow claims 1-16.

An oral hearing is desired and will be formally requested at the appropriate time pursuant to 37 CFR §1.194(b). Please charge our Deposit Account No. 08-2525, in the amount of $500.00, the requisite fee under 37 CFR §1.17(c). It is further requested that any deficiency or overpayment in connection with this fee be charged or credited to the above account.

Respectfully submitted,



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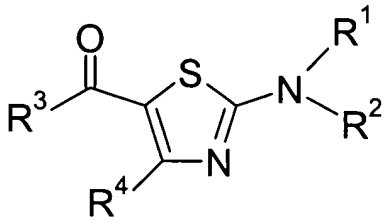
APPENDIX A

1. A compound of formula I:



(I)

wherein:

R^1 is aryl or heteroaryl, wherein at least one of the two meta positions of each aryl and heteroaryl group is substituted with R^5;

R^2 is hydrogen, alkyl or cycloalkyl;

R^3 is cycloalkyl or aryl , wherein at least one of the two ortho positions of each cycloalkyl or aryl group is substituted with R^6;

R^4 is hydrogen, alkyl or cycloalkyl;

R^5 is hydrogen, cyano, trifluoromethyl, alkyl-SO_2-, amino-SO_2-, halogen, alkoxy, alkylcarbonyl or aminocarbonyl; and

R^6 is hydrogen, halogen, cyano, nitro, trifluoromethyl, alkyl, alkoxy, hydroxy or alkoxycarbonyl;

or a pharmaceutically acceptable salt or ester thereof; with the proviso that one of R^5 and R^6 is not hydrogen and with the proviso that the following compounds are excluded:

(2,4-dichlorophenyl)-[2-[(3,4-dichlorophenyl)amino]-5-thiazolyl]-methanone,
(3,4-dichlorophenyl)-[2-[(3,4-dichlorophenyl)amino]-5-thiazolyl]-methanone,
[2-[(3,4-dichlorophenyl)amino]-5-thiazolyl]phenyl-methanone,
(4-bromophenyl)-[2-(3,4-dichlorophenyl)amino]-5-thiazolyl]-methanone,
(4-chlorophenyl)-[2-[3,4-dichlorophenyl)amino]-5-thiazolyl]-methanone,
[2-[(3,4-dichlorophenyl)amino]-5-thiazolyl](4-fluorophenyl)-methanone,
[2-[(2-chlorophenyl)amino]-5-thiazolyl](2,4-dichlorophenyl)-methanone and
(2,4-dichlorophenyl)-[2-(phenylamino)-5-thiazolyl-methanone.

2. The compound according to claim 1, wherein R^4 is hydrogen or methyl.

3. The compound according to claim 1, wherein R^2 is hydrogen.

4. The compound according to claim 1, wherein R^3 is cycloalkyl which is cylohexyl, aryl which is naphthyl or phenyl, wherein at least one of the two ortho positions of each cylohexyl, naphthyl and phenyl group is substituted with R^6.

5. The compound according to claim 4, wherein R^3 is aryl which is phenyl and wherein at least one of the two ortho positions of said phenyl group is substituted with R^6.

6. The compound according to claim 1, wherein R^1 is phenyl or pyridyl and, wherein at least one of the two meta positions of each phenyl or pyridyl group is substituted with R^5.

7. The compound according to claim 6, wherein R^5 is selected from cyano, trifluoromethyl, alkyl-SO_2-, amino-SO_2-, halogen, alkoxy, alkylcarbonyl and aminocarbonyl.

8. The compound according to claim 7, wherein R^5 is selected from cyano, trifluoromethyl, alkyl-SO_2-, amino-SO_2- and alkylcarbonyl.

9. The compound according to claim 8, wherein R^5 is selected from cyano, trifluoromethyl, methyl-SO_2-, NH_2-SO_2- and methylcarbonyl.

10. The compound according to claim 1, wherein R^6 is selected from halogen, cyano, nitro, trifluoromethyl, alkyl, alkoxy, hydroxy and alkoxycarbonyl.

11. The compound according to claim 10, wherein R^6 is selected from halogen, trifluoromethyl and alkyl.

12. The compound according to claim 1 selected from

3-[5-(2-Fluoro-benzoyl)-thiazol-2-ylamino]-benzonitrile;

3-[5-(2-Chloro-benzoyl)-thiazol-2-ylamino]-benzonitrile;

(2-Chloro-phenyl)-[2-(3-trifluoromethyl-phenylamino)-thiazol-5-yl]-methanone;

3-[5-(2-Methyl-benzoyl)-thiazol-2-ylamino]-benzonitrile;

o-Tolyl-[2-(3-trifluoromethyl-phenylamino)-thiazol-5-yl]-methanone;

1-{3-[5-(2-Methyl-benzoyl)-thiazol-2-ylamino]-phenyl}-ethanone;

3-[5-(2-Ethyl-benzoyl)-thiazol-2-ylamino]-benzonitrile;

3-[5-(2-Trifluoromethyl-benzoyl)-thiazol-2-ylamino]-benzonitrile;

[2-(3-Methanesulfonyl-phenylamino)-thiazol-5-yl]-o-tolyl-methanone;

(2-Ethyl-phenyl)-[2-(3-methanesulfonyl-phenylamino)-thiazol-5-yl]-methanone;

4-[5-(2-Ethyl-benzoyl)-thiazol-2-ylamino]-pyridine-2-carbonitrile;

4-[5-(2-Methyl-benzoyl)-thiazol-2-ylamino]-pyridine-2-carbonitrile;

3-[5-(2-Ethyl-benzoyl)-thiazol-2-ylamino]-benzenesulfonamide; and

3-[5-(2-Trifluoromethyl-benzoyl)-thiazol-2-ylamino]-benzenesulfonamide.

13. A pharmaceutical composition comprising a compound in accordance with claim 1 and a therapeutically inert carrier.

14. A method for the treatment or prophylaxis of obesity in a patient in need of said treatment, which comprises administering to said patient an effective amount of a compound of claim 1.

15. The method according to claim 14, wherein said compound is administered orally in an amount of from about 0.1 mg to 20 mg per kg per day.

16. The pharmaceutical composition of claim 13 further comprising a therapeutically effective amount of orlistat.